REMARKS

Reconsideration of the subject application in view of the preceding amendments and the following remarks is respectfully requested.

Claims 33-36, 38-42 and 45-48 and 50 are now pending in this application. In this amendment, Claims 37 and 49 have been cancelled without prejudice, and Claims 33, 34 and 38 have been replaced with amended Claims 33, 34 and 38. No new claims have been added. Claims 33, 34 and 38 have been amended to point out with greater specificity subject matter believed to be inherently included within the claims and/or correct formal deficiencies which the Examiner has brought to the Applicants' attention. A set of amended claims with insertions and deletions is appended hereto. No new matter has been added to the subject application by this amendment, nor have any new issues been raised.

The Office Action

In the outstanding Office Action, Claims 43 and 44 were withdrawn from consideration as being drawn to a nonelected species, Claims 34, 38, 41 and 49 were rejected for formal reasons under 35 U.S.C. §112, and Claims 33-42 and 45-50 were rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over U.S. Pat. No. 5,922,355. The Examiner also indicated that the information disclosure statement filed on December 26, 2002 failed to comply with 37 CFR 1.98(a)(2) and was therefore not considered.

Response by Applicant

Applicants' respectfully traverse the Examiner's rejections primarily because of the reasons set forth herein below. Applicants' have amended Claim 33 in accordance with the Examiner's comments recorded in the Interview Summary Sheet for the telephonic interviews that took place on January 23 and 27, 2003 with Applicants' representative. Applicants' have cancelled Claim 49 and amended Claims 34 and 38 to overcome the formal deficiencies described in the Office Action. With regard to Claim 41, Applicants' respectfully contend that there is ample support for the subject matter claimed throughout the specification, and in particular, on page 5, lines 1-14 of the specification.

Accordingly, Applicants' believe that Claims 33-36, 38-42, 45-48 and 50, as now claimed, are directed to patentable subject matter and in condition for allowance. In addition, a terminal disclaimer is filed herewith to obviate the double-patenting rejection. Thus, it is respectfully submitted that as a result of this amendment and discussion relating thereto, all of the claims presently pending in this application are in condition for allowance, and such action is earnestly solicited.

The Office Action indicates that the Examiner did not consider the information disclosure statement filed December 26, 2002. However, the information disclosure statement was attached to the outstanding Office Action with an indication that the Examiner did consider the cited references (*i.e.*, the Examiner has placed her initials next to the documents). Applicants' respectfully request that the Examiner clarify her position with regard to this matter. For purposes of efficient remediation, Applicants' would greatly appreciate an indication of which cited references, if any, do not comply with 37 CFR 1.98(a)(2).

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If the Examiner believes that a personal or telephonic interview may facilitate resolution of any remaining matters, Applicant's representative may be contacted at the number indicated below.

Respectfully submitted,

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Date: June 30, 2003

APPENDIX ILLUSTRATING REVISIONS TO THE CLAIMS

IN THE CLAIMS:

Please cancel Claim 37 and 49, *without prejudice.*

Please replace Claims 33, 34 and 38 with the following Amended Claims 33, 34 and 38 which read as follows:

--33.　(Amended)　A method of preparing fenofibrate microparticles [comprising preparing a mixture comprising an aqueous solution, fenofibrate particles, a phospholipid, and a surfactant, and applying energy to the mixture sufficient to produce a composition comprising fenofibrate microparticles,

wherein the surfactant is selected from the group consisting of casein, tragacanth, enteric resins, cholesterol esters, polyoxyethylene fatty alcohol ethers, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, poloxamers, polaxamines, polyvinyl alcohol, polyvinylpyrrolidone, potassium laurate, triethanolamine stearate, sodium lauryl sulfate, alkyl polyoxyethylene sulfates, sodium alginate, dioctyl sodium sulfosuccinate, negatively charged glycerol esters, quaternary ammonium compounds, chitosans, colloidal clays, sodium dodecylsulfate, sodium deocycholate, and combinations thereof.] including a particle size reduction process such as sonication, homogenization, milling, microfluidization, recrystallization, and precipitation, or a combination thereof, the method comprising the steps of:

(1) mixing the fenofibrate particles with (a) a natural or synthetic phospholipid and (b) at least one non-ionic, anionic or cationic surfactant, prior to or during the particle size reduction process, and thereafter

(2) applying energy to the mixture sufficient to produce fenofibrate microparticles having a volume-weighted mean particle size value that is about 50% smaller than particles produced without the presence of the surfactant using the same energy input.--

--34.   (Amended)   The method of claim 33, wherein [the mixture comprises] step (1) further comprises mixing the fenofibrate particles with (a) at least two phospholipids and at least one surfactant, (b) a phospholipid and at least two surfactants, or (c) at least two phospholipids and at least two surfactants.--

--38.   (Amended)   The method of claim 33, wherein the fenofibrate particles are 5-100 μm in size, such that the fenofibrate microparticles [are at least 80% smaller than the particles.] have a volume-weighted mean particle size value that is about 80% smaller than particles produced without the presence of the surfactant using the same energy input.--